



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

10

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,057	07/06/2001	Fayad Z. Sheabar	4532660/29930	7817

7590

07/28/2005

Daniel A. Rosenberg
Suite 2500
The Financial Center
666 Walnut Street
Des Moines, IA 50309

EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,057

Applicant(s)

SHEABAR ET AL.

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18 are pending in the application and were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-10, 17 and 18 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,767,566 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-18 are made obvious by claims 1-10 of '566 in light of the Specification.

Claims 1-10 of '566 teach every element of Instant claims 1-4, 7-10, 17 and 18 except for heating the extract material and the particular temperatures to where the extract is heated. One of ordinary skill in the art would have been motivated to heat the extraction slurry to the specific temperatures as recited in claims 4 and 7 because claim 1 of '566 recites '(d) recovering said liquid fraction from said slurry to obtain a proteinase inhibitor'. It is clear from the Specification that the only 'recovery' step, is heating of the slurry to obtain a precipitate (see Example 1, where the slurry is heated to 70 °C for 10 min.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'other protein products'. This phrase is newly found to be ambiguous. What 'other protein products' is Applicant referring to? Are these all proteins in the potato, or a certain portion of the proteins?

Claim Rejections - 35 USC § 103

Claims 1, 4-5, 7-12 and 17-18 are rejected under 35 USC 103(a) as being unpatentable over Borud et al. (EP 0487 480 A2) for the reasons of record.

Claim 6 is rejected under 35 USC 103(a) as being unpatentable over Borud as applied to claims 1, 4-5 and 7-12 above and further in view of Pearce et al. (1983) or Bryant et al. (1976) for the reasons of record.

Claims 13-16 are rejected under 35 USC 103(a) as being unpatentable over Borud as applied to claims 1, 4-5 and 7-12 above, and further in view of Ryan et al. (WO 99/01474) for the reasons of record.

Applicant's arguments pertaining to these rejections were fully considered, but not found persuasive.

Applicant argues that 'the addition of SO₂ is eliminated through the use of an organic acid' (p.2, Arguments). However, it is noted that the Instant claims state 'comprising' which is open language, allowing the incorporation of other, additional method steps which are not specifically disclosed in the Instant specification

Further, Applicant argues that the organic acid of the Instant claims would not act as a functional equivalent to the HCl as disclosed by Borud. Applicant explains the concept of acid-base reactions, pKa and buffering systems. It is first pointed out that Applicant has not suggested any significant role of an organic acid in the Specification itself, or any unexpected results achieved with the use of an organic acid over HCl of the prior art. What is well known in the art of protein purification is that proteins are commonly and traditionally precipitated from solutions with acids and salts to achieve the isoelectric point of the protein (the solubility threshold of the protein). This is conventional practice in the art of protein purification. Therefore, with regard to the nature of the Invention, formic acid and HCl would have acted as 'functional equivalents' in that each were used for, and achieved the same purpose; precipitation of the target proteins. The Examiner is not concluding, and concedes that formic acid and HCl are not the same acid and therefore have different properties. However, adjustment of

Art Unit: 1655

particular acids for protein purification is considered routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the functional equivalents involves only routine skill in the art. Here, determination of the optimum pH where the target proteins precipitated would have been well within the purview of the ordinary artisan and easily measured with a pH electrode.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to substitute a weak organic acid for the HCl as disclosed by Borud as they would have achieved similar results with regard to precipitation of the protein. Applicant states that "adding HCl will result in the degradation/denaturation of the protein, while organic acid will not" (p. 3, Arguments). However, this statement is unsubstantiated. HCl is often used to titrate solutions containing proteins to the protein's isoelectric point(s) (well established in the art). Further, the extent to which HCl will lower the acidity of a solution is dependant upon the molarity of the acid. Borud added HCl to the slurry to obtain a pH of 4.4, but there is no indication that Borud made the slurry so acidic that proteins were actually denatured. Also, Applicant has not indicated that a pH of 4.4 would denature the target protein. It is further noted that most of the claims simply state 'organic acid'. Although Applicant argues that (the strength of) HCl will denature the proteins, it is noted that all organic acids are not good buffers. Some organic acids such as benzoic acid are considered strong acids which are within the metes and bounds of claims which simply state 'organic acid'.

Applicant argues 'the cited art does not describe or suggest the time and temperature effects on the final purity of the recovered protein fraction that are described in the present application' (p. 3, Arguments). Here, it is not understood which time and temperature effects Applicant is referring to. Further, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the combined references do not 'meet the purpose of the claimed invention' and therefore the claimed invention is patentably distinct over the prior art references (p.3, Arguments). However, as explained *supra*, it is considered that the choice of an organic acid would have been obvious to one of ordinary skill in the art at the time the invention was made. The choice of an organic acid is considered a functional equivalent to HCl in the present instance because it achieves the same basic effect as HCl; precipitation of the target proteins. The ordinary artisan would have recognized that many acids could have been substituted for HCl with minor adjustments to volume, size and salinity in order to precipitate the proteins out of solution. These types of variables are routinely optimized through routine experimentation as discussed *supra*.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

Art Unit: 1655

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/900,057
Art Unit: 1655

Page 9

Patricia Leith
Primary Examiner
Art Unit 1655

6/30/05

A handwritten signature in cursive script, appearing to read "Patricia Leith", written in black ink.